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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,721	08/17/2001	Yoshio Hiraki	2114631US0PC	2653

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/13/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/913,721

Applicant(s)

HIRAKI ET AL.

Examiner

Gina C. Yu

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED July 8, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.


NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): claim rejection under 35 U.S.C. § 112, second par..
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-13.Claim(s) withdrawn from consideration: None.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


RUSSELL TRAVERS
PRIMARY EXAMINER

Continuation from No. 5:

Applicants state that the addition of secondary lipid as in Mathur would change the basic and novel characteristics of the claimed invention. Examiner notes that it is well settled in patent law that if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also MPEP § 2111.03. Examiner reiterates that there must be a clear indication in the specification or claims of what the basic and novel characteristics are, and the transitional phrase "consisting essentially of" will be construed as "comprising". See PPG Industries v. Guardian Industries, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998). In this case, examiner views that there is no clear indication either in the specification or claims that the basic and novel characteristics of the claimed invention is using only mono fatty acid monoglyceride as the only lipid in the lamellar composition. Besides the mono fatty acid monoglyceride, cholesterol is also used in every example formulations in the specification. See spec. Table 6. It is also noted that monostearyl or monopalmityl glyceryl ethers are used in the compositions therein. Claim 11 also recites that the composition 'further comprises' cholesterol. While applicants assert that cholesterol is a mere additive, applicants' own disclosure seem to indicate that cholesterol is a required element in the formation of lamellar structure. Thus examiner cannot agree that the basic and novel characteristic of the claimed invention is using

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only mono fatty acid glyceride and vitamin A to obtain a lamellar structure. Examiner thus takes the position that the limitation of the instant claim 1 should be construed as an open limitation to include lipids other than the recited mono fatty acid glyceride.

Examiner notes that the Mathur refers cholesterol as an "additive" and not a "secondary lipid", however, it must be noted that the obviousness rejection is maintained because the limitation of the instant claims are still construed as open limitation. The Mathur reference clearly teaches, and every single example therein illustrates, using cholesterol to form lamellar phases. See Mathur, col. 3, line 40 – col. 4, line 14; Examples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.


RUSSELL TRAVERS
PRIMARY EXAMINER